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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,942	07/11/2003	Seishi Kato	01997.017300.2	3026
45743	7590	12/22/2004	EXAMINER	
FITZPATRICK CELLA (WYETH)			DEBERRY, REGINA M	
30 ROCKEFELLER PLAZA			ART UNIT	
NEW YORK, NY 10112-3800			PAPER NUMBER	
			1647	

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/616,942

**Applicant(s)**

KATO ET AL.

**Examiner**

Regina M. DeBerry

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

***Status of Application, Amendments and/or Claims***

The amendment filed 28 October 2004 has been entered in full. Claims 19-30 are under examination.

The information disclosure statement (IDS) filed 28 October 2004 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

The specification is in compliance with 37 CFR 1.821-1.825 of the Sequence Rules and Regulations.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Objections And/Or Rejections***

The objection to specification, as set forth at page 3 of the previous Office Action (16 September 2004) is *withdrawn* in view of the amendment (28 October 2004).

The rejection to claim 28 under 35 U.S.C. 112, second paragraph, as set forth at page 12 of the previous Office Action (16 September 2004) is *withdrawn* in view of the amendment (28 October 2004).

The rejection to claim 26 under 35 U.S.C. 112, first paragraph, written description, as set forth at pages 10-12 of the previous Office Action (16 September

2004) is *withdrawn*. The Examiner mistakenly interpreted SEQ ID NO:9 as a variant polynucleotide.

**Claim Rejections - 35 USC § 101 - 35 USC § 112, First Paragraph, Enablement**

Claims 19-30 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. The basis for this rejection is set forth at pages 5-10 of the previous Office Action (16 September 2004).

Applicant points out that SEQ ID NO:3 is identified as a subunit of NADH:ubiquinone oxidoreductase (Complex I), as evidenced by both BLAST search and Carroll, J. *et al.*, JBC (2002) 277(52), 50311-17. Applicant states that Murray, *et al.*, JBC (2003) 278(16), 13619-22, confirms that inhibition of Complex I is implicated in neurodegenerative disorders, including Parkinson's, as mentioned at specification page 29, line 19. Applicant submits copies of the cited references.

Applicant's arguments have been fully considered but not deemed persuasive. Applicant does not state the specific BLAST search. The Examiner assumes that Applicant is referring to the BLAST search cited in the specification for SEQ ID NOs:3, 9 and 17 (specification, page 50, lines 3-4; Accession No. N56722). The description for Accession No. N56722 (Hillier *et al.*) does not teach a subunit of NADH:ubiquinone oxidoreductase (Complex I) or teach SEQ ID NO:3 as a subunit of NADH:ubiquinone oxidoreductase (Complex I).

The references submitted by Applicant teach the isolation of Complex I from heart tissue. Carroll *et al.* describe the isolation of bovine heart mitochondrial Complex I (NADH:ubiquinone oxidoreductase). Carroll *et al.* state that Complex I from bovine mitochondrial has a molecular mass of over 900 kDa and that a total of 43 subunit sequences have been reported. Murray *et al.* describe the isolation of human NADH dehydrogenase from human heart mitochondria. Murray *et al.* state that a total of 42 different component polypeptides were identified. Murray *et al.* state, "it is difficult to establish whether any subunit is a bona fide subunit or an associated impurity of a complex until the stoichiometry of that polypeptide has been determined and/or a key functional role has been identified." "In the case of three polypeptides listed above, there are functions ascribed to each, that are not related to Complex I activity" (page 13622, first paragraph).

The submitted references are not found persuasive for the following reasons. The references do not teach which subunit of Complex I is SEQ ID NO:3. An amino acid sequence alignment of SEQ ID NO:3 and a specific subunit of Complex I was not submitted. Furthermore, even if SEQ ID NO:3 and a subunit of Complex I were found to be identical, the rejection would be maintained because the instant references fail to teach a specific function for the subunits. Murray *et al.* state that key functional roles need to be identified. The Examiner agrees with Applicant. Murray *et al.* state that there is strong evidence that Complex I inhibition, through accumulated damage caused by reactive oxygen and nitrogen species and by the binding of environmental toxins, has a role in the development of the more prevalent neurodegenerative disorders including

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Parkinson's disease. However, the statement implies that the entire Complex I contributes to the development of the recited neurodegenerative diseases. Thus, it is unclear if one subunit would have any affect on Parkinson's disease. The references teach that Complex I is made up of over 40 different subunits. The instant specification has only purported to isolating one subunit (SEQ ID NO:3) of Complex I. A correlation between SEQ ID NO:3 and Parkinson's disease has not been established.

Claims 19-30 remain rejected under 35 U.S.C. 112, first paragraph. The basis for this rejection is set forth at page 10 of the previous Office Action (16 September 2004). Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

#### **Claim Rejections - 35 USC § 112, Second paragraph**

Claims 29 and 30 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The basis for this rejection is set forth at page 12 of the previous Office Action (16 September 2004).

Applicant states that the rejection of claims 29 and 30 is mooted by the amended

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claim 26. Applicant's arguments have been fully considered but not deemed persuasive. Claims 29 and 30 depend from claim 28. Claim 28 is drawn to an isolated host cell comprising the polynucleotides of any one of claims 23-26. The problem lies with the recitation "complement" (claims 23-26). Claims 23-26 recite an isolated polynucleotide or *a complement of* said isolated polynucleotide. A isolated host cell comprising a non-coding strand will not be transcribed and translated. As was stated in the previous Office Action (16 September 2004, page 12), scientifically, a polypeptide cannot be made from a non-coding strand.

Amended claim 26 is rejected under 35 U.S.C. 112, second paragraph, because it recites the limitation "wherein said isolated polypeptide". There is insufficient antecedent basis for this limitation in the claim. Deleting "wherein said isolated polypeptide is involved in Parkinson's disease" would obviate the rejection.

### **Conclusion**

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*RMD*  
RMD  
12/16/04

*Elizabeth C. Kemmer*